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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/610,152	07/05/00	FERRARA	N 9491-043-27

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EXAMINER

WEBER, J

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/610,152	Applicant(s) FERRARA ET AL.	
	Examiner Jon P. Weber, Ph.D.	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

Status of the Claims

Claims 8-15 have been presented for examination.

Election/Restrictions

Applicant's election with traverse of Group I, claimed 8-13 in Paper No. 5, filed 18 April 2001 is acknowledged. The traversal is on the ground(s) that there would be no burden of search because the groups are at least partially co-extensive. This is not found persuasive because search burden was established because there are two active ingredients in the composition of Group II; a reference disclosing the first active ingredient, HGF, would not anticipate or render obvious a combination of the first and a second active ingredient, VEGF.

The requirement is still deemed proper and is therefore made FINAL. Claims 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites "recombinant HGF" which is vague and indefinite because it is not clear if HGF is produced recombinantly or itself has been recombined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al.

(1993).

Rosen et al. (1993) disclose at page 231, second full paragraph, that hepatocyte growth factor (HGF) from mouse and human give a similar dose-dependent angiogenic response upon implantation of Hydron pellets containing entrapped HGF into avascular rat cornea *in vivo*. In a second assay at page 231, first full paragraph, dose-dependent angiogenesis was also observed with HGF entrapped in Matrigel (basement membrane) in liquid form which was injected into the subcutaneous tissue of mice. See also the Summary at page 227.

Claims 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarnegar et al.

(1993).

Zarnegar et al. (1993) disclose that the pluripotent hepatocyte growth factor/scatter factor (HGF-SF) has as one of its many activities the ability to promote angiogenesis in vascular epithelial cells (summary; page 183, second full paragraph). The release of HGF-SF into the blood from various tissues such as lung, kidney and liver following injury suggests a role for HGF-SF in both angiogenesis and vascular repair. Human and rat HGF have been most well studied.

Claims 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Grant et al. (1993).

Grant et al. (1993) disclose that scatter factor (SF a.k.a. HGF) induces blood vessel formation *in vivo* in a dose-dependent manner in an avascular rat corneal implant and in a subcutaneous injection of HGF in Matrigel in mouse. Mouse SF and human HGF were used.

Claims 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bussolino et al. (1992).

Bussolino et al. (1992) disclose that HGF is a potent angiogenic factor which stimulates angiogenesis *in vivo* in a dose-dependent manner. Both human and murine HGF were used. In the angiogenic assay *in vivo* described at page 631, column 2, HGF was encapsulated in a vinyl copolymer pellet which was then implanted in rabbit cornea. The *in vivo* results are provided at pages 636-638.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen et al. (1993), Zarnegar et al. (1993), Grant et al. (1993) or Bussolino et al. (1992) in view of Godowski et al. (1994).

The teachings of Rosen et al. (1993), Zarnegar et al. (1993), Grant et al. (1993) and Bussolino et al. (1992) have been discussed above. Rosen et al. (1993), Zarnegar et al. (1993), Grant et al. (1993) and Bussolino et al. (1992) lack recombinant HGF.

A person of ordinary skill in the art at the time the invention was made would have been motivated to because provide a pharmaceutical composition for vascular tissue comprising recombinantly produced HGF because of Godowski et al. (1994) show that recombinant HGF was known in the art and was a suitable replacement for the naturally occurring enzyme for the advantages of purification and yield which are well known in the art.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use recombinantly produced HGF in a pharmaceutical.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the

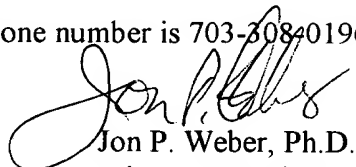
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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW

June 15, 2001